

**Translation**

**PATENT COOPERATION TREATY**

PCT/JP2003/016036



**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 145372-081	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/JP2003/016036	International filing date ( <i>day/month/year</i> ) 15 December 2003 (15.12.2003)	Priority date ( <i>day/month/year</i> ) 13 December 2002 (13.12.2002)	
International Patent Classification (IPC) or national classification and IPC C07D 513/04, 519/06, C07F 9/6561			
Applicant MEIJI SEIKA KAISHA, LTD.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I      Basis of the report</p> <p><input type="checkbox"/> Box No. II      Priority</p> <p><input type="checkbox"/> Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV      Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V      Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI      Certain documents cited</p> <p><input type="checkbox"/> Box No. VII      Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII      Certain observations on the international application</p>	

Date of submission of the demand 14 June 2004 (14.06.2004)	Date of completion of this report 02 December 2004 (02.12.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/016036

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))  
☐ publication of the international application (under Rule 12.4)  
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the claims:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the drawings:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/16036

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)

Claims

1-37

YES

Claims

NO

Inventive step (IS)

Claims

2, 11-20, 22-24, 31, 32, 34-36

YES

Claims

1, 3-10, 21, 25-30, 33, 37

NO

Industrial applicability (IA)

Claims

1-37

YES

Claims

NO

## 2. Citations and explanations (Rule 70.7)

1. WO, 02/42312, A1 (Meiji Seika Kaisha, Ltd.), 30 May 2002, and AU, 2002024088, A1 & EP, 1336612, A1.
2. WO, 01/53305, A1 (Meiji Seika Kaisha, Ltd.), 26 July, 2001 & 2001027095, A1.
3. JP, 8-311071, A (Meiji Seika Kaisha, Ltd.), 26 November 1996 (Family: none).
4. WO, 01/55155, A1 (Meiji Seika Kaisha, Ltd.), 02 August, 2001 & AU, 2001028833, A1 & EP, 1251134, A1 & US, 2003/022881, A1.

Claims 1, 3 to 10, 21, 25 to 30, 33, and 37

The inventions described in claims 1, 3 to 10, 21, 25 to 30, 33, and 37 appear to possess novelty with respect to documents 1, 2 cited in the ISR, but do not appear to involve an inventive step based on documents 1, 2.

Document 1 relates to a method for the manufacture of a carbapenem derivative corresponding to the compound represented by Formula (A) of claim 27 and describes that a trialkyltin compound of substituted imadazo[5, 1-b] thiazol is used when a substitution group is introduced in position 2 of the carbapenem (in particular see schemes 1-3 and working example 2).

Document 2 relates to a method for the manufacture of a carbapenem derivative having substituted imadazo[5, 1-b] thiazol group analogous to the substitution group described in document 1 in position 2 and describes that in order to produce this derivative effectively with high safety and cost efficiency, without using an organotin compound, the substituted imadazo[5, 1-b] thiazol group is treated with a Grainier reagent and reacted with an azethiazine derivative which is a precursor for the carbapenem group (in particular, see pages 2, 16, claims).

Here, selecting the optimum reaction conditions with the object of improving the yield and simplifying the production process is usually conducted by a person skilled in the art. Therefore, the manufacturing method described in document 2 could have easily been used by a person skilled in the art instead of the manufacturing method described in document 1 when manufacturing the compound represented by Formula (A) of claim 27 according to the description provided in document 2.

Further, the compounds described in claims 1, 3 to 7, and 33 can be easily obtained in an intermediate manufacturing stage of the above-mentioned manufacturing method that can be easily implemented.

(Continued)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of Box V:

Claims 2, 11 to 20, 22 to 24, 31, 32, and 34 to 36

The inventions described in claims 2, 11 to 20, 22 to 24, 31, 32, and 34 to 36 appear to possess novelty and involve an inventive step based on documents 1-4 cited in the ISR.

The inventions described in claims 2, 11 to 20, 22 to 24, 31, 32, and 34-36 are neither described nor suggested in documents 1 and 2.

The inventions described in claims 31, 32, and 36 are neither described nor suggested in documents 3 and 4 (in particular, see claims of document 3, Par. Nos. [0022]-[0025] and pages 52-54, Synthesis Example 1 of document 4).